K001423

JUL 21 2000

EXHIBIT 1-1

510(K) SUMMARY

1. SUBMITTER

KAWASUMI LABORATORIES, INC.
3-28-15 MINAMI-OHI
SHINAGAWA-KU, TOKYO 140 JAPAN
PHONE:81-3-376-1151
FAX: 81-3-376-3235
CONTACT: MR. S. SUWA

AGENT

KAWASUMI LABORATORIES AMERICA, INC.
5909 C HAMPTON OAKS PARKWAY
TAMPA, FL 33610
PHONE: 813-630-5554
FAX: 813-630-5033
CONTACT: MR. JACK PAVLO

2. **NAME OF DEVICE**: KAWASUMI LABORATORIES IV ADMINISTRATION SET, PRIMARY

   COMMON NAME: ADMINISTRATION SET, IV SET

3. **PREDICATE DEVICE**: KAWASUMI LABORATORIES IV ADMINISTRATION SET K896895

4. **DESCRIPTION OF THE DEVICE**: THE IV ADMINISTRATION SET IS A NON-DEHP FLUID PATH DEVICE WITH SPIKE TO PENETRATE THE SOLUTION CONTAINER, DRIP CHAMBER, AND REGULATING CLAMP USED TO CONTROL THE SOLUTION FLOW TO THE PATIENT. THE SET INCLUDES A POLYETHERSULFONE .2 MICRON FILTER. THE SET MAY INCLUDE A Y CONNECTOR TO ACCESS THE SET. THE SET MAY ALSO INCLUDE A SWABABLE, NON-CAPPED, NEEDLELESS ACCESS CONNECTOR WHICH ELIMINATES THE USE OF A NEEDLE TO ACCESS THE SET AND AIDS IN THE PREVENTION OF NEEDLESTICK INJURIES.

5. **INTENDED USE**: THE IV ADMINISTRATION SET IS A STERILE, SINGLE USE DEVICE USED AS A CONDUIT FOR INTRAVASCULAR SOLUTION ADMINISTRATION.

6. **TECHNOLOGICAL CHARACTERISTICS**: THERE ARE NO TECHNOLOGICAL CHARACTERISTICS OF THIS DEVICE TO THE SUBSTANTIALLY EQUIVALENT DEVICE FROM KAWASUMI LABORATORIES BEING MARKETED FOR SALE IN INTERSTATE COMMERCE.

7. **PERFORMANCE DATA**: KAWASUMI LABORATORIES HAS CONDUCTED BIOCOMPATIBILITY TESTS ON THE BODY FLUID CONTACTING MATERIAL PORTIONS OF THE DEVICE AND KL BELIEVES THE BIOCOMPATIBILITY DATA SHOW THE DEVICE IS SUITABLE FOR ITS INTENDED USE.

8. **CONCLUSIONS**: THE DEVICE MEETS ALL BIOCOMPATIBILITY AND PYROGENICITY TEST REQUIREMENTS. THEREFORE, IT IS AS SAFE AS THE PREDICATE DEVICE AND PERFORMS AS WELL AS THE PREDICATE DEVICE.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 21 2000

Mr. Jack Pavlo
Kawasumi Laboratories America, Incorporated
P.O. Box 24355
Tampa, Florida 33623-4355

Re: K001423
Trade Name: Kawasumi Laboratories IV Administration Set, Primary
Regulatory Class: II
Product Code: FPA
Dated: June 29, 2000
Received: June 30, 2000

Dear Mr. Pavlo:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K001423

EXHIBIT 1-2

510(k) Number (if known): K001423

Device Name: IV Administration set, Primary

Indications for Use:

THE IV ADMINISTRATION SET IS A DEVICE USED TO SERVE AS A CONDUIT FOR THE DELIVERY OF IV FLUIDS FROM A CONTAINER TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. THE DEVICE MAY INCLUDE A NEEDLELESS ACCESS CONNECTOR WHICH ELIMINATES THE USE OF NEEDLES TO ACCESS THE SET DURING IV ADMINISTRATION AND AIDS IN THE PREVENTION OF NEEDLESTICK INJURIES.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K001423